UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

**Note to Reader**
**January 8, 1998**

**Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.**

**The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.**

**There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.**

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

**Note:** This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket ( RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

**OFFICE OF**
**PREVENTION, PESTICIDES AND**
**TOXIC SUBSTANCES**

July 21, 1998

MEMORANDUM

SUBJECT: Pirimiphos-methyl. (Chemical ID No. 108102/List B Reregistration Case No. 2535). Acute and Chronic Dietary Risk Analyses. No MRID #. DP Barcode No. D245961.

FROM: Christina B. Swartz, Chemist
Reregistration Branch 1
Health Effects Division (7509C)

THRU: Whang Phang, Ph.D., Branch Senior Scientist
Reregistration Branch 1
Health Effects Division (7509C)

TO: Merle Sykes/Arnold Layne (PM-51)
Accelerated Reregistration Branch
Special Review and Reregistration Division (7508W)

## Action Requested

In conjunction with completion of a residue chemistry chapter of the HED RED, an anticipated residue assessment has been conducted for the organophosphate active ingredient pirimiphos-methyl. Based on anticipated residues in commodities associated with the post-harvest use on grain, and on toxicological endpoints selected for acute and chronic dietary exposure, both acute and chronic dietary risk assessments should be conducted using the Dietary Exposure Evaluation Model (DEEM™).

## Toxicological Information

The HED Hazard Identification Assessment Review Committee (HIARC) met 1/12/98 to select a dose and endpoint for acute dietary risk assessment; in addition, the committee reassessed the reference dose (RfD) established for chronic dietary risk assessment. Finally, the committee addressed special sensitivity to infants and children as required by the Food Quality Protection Act (FQPA) of 1996. The conclusions of the Committee for pirimiphos-methyl were presented in a memo dated 1/29/98 (J. Rowland). In meetings conducted to assess consistency in selecting endpoints and safety factors for all organophosphates, changes were made to the conclusions of the HIARC. These are summarized in the relevant sections, below.

*Acute Dietary*

Two oral studies conducted in humans were selected for establishing an acute dietary endpoint and NOEL. The 56-day and 28-day oral toxicity studies were summarized in the Committee report. Cholinesterase inhibition was not observed in either study prior to day 14; however, only one dose was tested, 0.25 mg/kg/day, and it was presumed that cholinesterase inhibition could have occurred at higher doses. The dose selected for risk assessment (acute dietary) was the no observable effects level (NOEL) of 0.25 mg/kg/day, based on a lack of cholinesterase inhibition up to day 7 of the study [it was believed that cholinesterase inhibition could have occurred at higher doses].

Although the results of available developmental and reproduction studies showed no increased sensitivity to either developing fetuses or to pups, the FQPA safety factor was retained, but reduced to 3X, because the Committee concluded that the database was inadequate to evaluate acute delayed neurotoxicity following a single exposure, to assess the functional development of young animals, and, in turn, the susceptibility to infants and children, and to determine the need for a developmental neurotoxicity study. For acute dietary risk assessment, a margin of exposure (MOE) of 30 is required, 10X for intra-species variation, and 3X as required under FQPA. The acute dietary reference dose (aRfD), modified in accordance with FQPA, is 0.0083 mg/kg body weight/day.

*Chronic Dietary*

In 1988, the reference dose (RfD) for chronic dietary risk assessment was selected from a 56-day oral toxicity study in humans; the reference dose was reassessed in the 1/12/98 HIARC meeting, pursuant to FQPA. While the Committee selected the same dose/endpoint for establishing the RfD, the Committee determined that the only dose tested, 0.25 mg/kg/day, should be considered a LOEL (lowest observable effects level), rather than a NOEL, based on statistically significant plasma cholinesterase inhibition in 3 females between days 14 and 35.

The Committee applied an uncertainty factor of 1,000, based on the retention of the 3X safety factor as required under FQPA (see above), a 3X for a lack of a true NOEL, a 10X for intra-species variation, and an additional 10X for data gaps (chronic toxicity in dogs, chronic toxicity/carcinogenicity in rats, and a delayed neurotoxicity study in hens). Therefore, based on the LOEL of 0.25 mg/kg/day and on the uncertainty factor of 1,000X, the reference dose (RfD) for chronic dietary risk assessment, adjusted in accordance with FQPA, is 0.00025 mg/kg/day.

*Carcinogenicity*

The HIARC concluded that the currently available data did not indicate a significant increase in tumor incidence in the treated animals; however, the data were not adequate to assess the carcinogenic potential of pirimiphos-methyl. Pending receipt of a chronic/carcinogenicity study in rats, a dietary risk assessment for carcinogenicity may be required.

**Residue Information**

Pirimiphos-methyl is registered for post-harvest use on stored corn and sorghum grain; in addition, products consisting of impregnated materials (ear tags) are registered for application to cattle. For the purpose of this assessment, the only food use for pirimiphos-methyl is the post-harvest use on stored grain. Anticipated residues were generated in conjunction with completion of a residue chemistry chapter in which a tolerance reassessment summary was presented, and the status of the residue chemistry database was summarized.

The following anticipated residues (ARs) were specified [refer to the HED residue chemistry chapter, C. Swartz memo dated 6/1/98] for use in acute and chronic dietary risk assessments (note that % crop treated data provided by BEAD have already been incorporated into the anticipated residues, and therefore should not be applied during the dietary risk analysis):

Table 1. Summary of Anticipated Residues (ARs) for Acute/Chronic Dietary Risk Assessment.

| Commodity[1] | Reassessed Tolerance (ppm)[2] | Average Residue (ppm)[3] | Acute AR (ppm)[4] | Chronic AR (ppm)[5] |
|---|---|---|---|---|
| corn, grain | 8 | 2.51 | 2.51 | 0.351 |
| corn, oil | 60 | 30.6 | 30.6 | 4.28 |
| sorghum, grain | 8 | 3.90 | 3.90 | 0.039 |
| cattle, mbyp | 0.02 | n/a | 0.04 | 0.000162 |
| cattle, fat | 0.02 | n/a | 0.04 | 0.000297 |
| poultry, fat | 0.02 | n/a | 0.04 | 0.000352 |

[1] Based on available residue chemistry data, HED recommends revocation of tolerances for residues in wheat, rice, kiwi fruit, meat (of cattle, goats, hogs, horses and sheep), milk, poultry meat and eggs, and in milled fractions of grain. Therefore, the commodities shown in the table [and their associated processed commodities] are the only commodities to be incorporated into acute/chronic dietary risk assessments. Since residues do not concentrate in grain milled fractions (with the exception of corn oil), the anticipated residues determined for grains should be used for these commodities in the risk analysis.

[2] The tolerance reassessment summary wa included in the HED residue chemistry chapter dated 6/1/98 (DP Barcode No. D240744).

[3] Average residues in corn and sorghum grain were determined from residue trials. The residue in corn oil was based on the average residue in corn grain, and the average concentration factor of 12.2X for corn oil.

[4] Although HED normally uses tolerance-level residues in the acute dietary risk analysis, average

residues can be used for blended commodities, such as grains and oil. For livestock commodities, the anticipated residue is higher than the tolerance since it must incorporate residues of both parent and the des-ethyl metabolite.

[5] The anticipated residues have been corrected for % crop treated (<1% for sorghum, and 15% for corn). The % crop treated (%CT) data were generated by BEAD in conjunction with completion of the RED; after discussion with BEAD regarding discrepancy between monitoring data and % crop treated, the % CT for corn was revised to include treatment of food corn only.

## Results

The DEEM™ Software estimates dietary exposure to pesticides in foods based on the 3-day average of consumption data collected in USDA's Continuing Surveys of Food Intake by Individuals, 1989-1992. Using toxicological parameters specified by HED's HIARC, DEEM™ expresses dietary risk as a function of dose through dietary exposure. The results for pirimiphos-methyl are shown in Tables 2 (chronic dietary risk) and 3 (acute dietary risk).

Table 2. Chronic Dietary Risk Calculated Using DEEM™, Expressed as a Percentage of the Chronic Dietary RfD (adjusted in accordance with FQPA).

| Population Subgroup | Exposure (mg/kg body wt/day) | Percent of RfD |
|---|---|---|
| U.S. Pop - 48 states - all seasons | 0.000564 | 226 |
| All infants (<1 year) | 0.000685 | 274 |
| Nursing infants (<1 year) | 0.000217 | 87 |
| Non-nursing infants (<1 year) | 0.000882 | 353 |
| Children (1-6 years) | 0.001262 | 505 |
| Children (7-12 years) | 0.000975 | 390 |
| Females (13-19 yrs/not preg. or nursing) | 0.000568 | 227 |
| Males (13-19 years) | 0.000714 | 285 |

Table 3. Acute Dietary Risk Calculated Using DEEM™, Expressed as a Percentage of the Acute Dietary RfD (adjusted in accordance with FQPA).

| Population Subgroup | 95th Percentile | | 99th Percentile | | 99.9 Percentile | |
|---|---|---|---|---|---|---|
| | Exposure | % aRfD | Exposure | % aRfD | Exposure | % aRfD |
| U.S. pop - all seasons | 0.011888 | 143 | 0.020468 | 247 | 0.035613 | 429 |
| Nursing infants (<1yr) | 0.007220 | 87 | 0.008961 | 108 | 0.009260 | 112 |
| Non-nursing infants (<1 yr) | 0.022065 | 266 | 0.042357 | 510 | 0.144424 | 1740 |
| Children (1-6 yrs) | 0.022578 | 272 | 0.033098 | 399 | 0.052161 | 628 |
| Children (7-12 yrs) | 0.016447 | 198 | 0.024378 | 294 | 0.040685 | 490 |

The results of the DEEM™ analysis indicate that both acute and chronic dietary risk exceed the Agency's level of concern for all population subgroups. Examination of the commodity contribution analysis reveals that essentially all of the chronic dietary risk is due to residues in corn commodities, the most significant contributor being high fructose corn syrup (HFCS), at an average of 70% of the chronic dietary risk. Note that since there are no processing data to determine a concentration/reduction factor for high fructose corn syrup, the anticipated residue in corn grain was translated to HFCS in the DEEM™ analysis. There are no data indicating whether residues actually occur in HFCS, but HED notes that pirimiphos-methyl residues do not concentrate in corn commodities other than oil.

Although there is no tolerance established for residues in popcorn, this commodity was included in the analysis since the use is post-harvest on the grain, and would not preclude treatment of popcorn. In addition, FDA monitoring data indicated that residues are likely to occur in popcorn.

Refer to the attached DEEM™ analysis for details.

Attachment: Chronic and Acute DEEM™ analyses for pirimiphos-methyl.

Secondary Review: Carol Lang/Brian Steinwand:07/16/98; Brenda Tarplee:07/13/98

cc (with attachment): Reviewer (Cswartz); Brian Steinwand (CEB1/HED, 7509C)
cc (without attachment): List B Rereg. File; SF
7509C:CSwartz:RRB1:CM2:Rm 804F:703 305 5877:07/10/98

U.S. Environmental Protection Agency
DEEM89N CHRONIC analysis for PIRIMIPHOS-METHYL
Residue file name: CHRONIC
Analysis Date 07-21-1998
Reference dose (RfD, CHRONIC) = 0.000250 mg/kg body-wt/day
COMMENT 1: The chronic NOEL is actually a LOEL
COMMENT 2: RfD incorporates OP Marathon Conclusions

Ver. 6.12
(1989-92 data)
Adjustment factor #2 NOT used.
Residue file dated: 07-21-1998/11:38:31/8

Residue file listing

| Food Code | EPA Code | Crop Group | Food Name | Residue (ppm) | Adj. Fctrs #1 | #2 |
|---|---|---|---|---|---|---|
| 237 | 15004AA | O | CORN/POP | 0.351000 | 1.00 | 1.00 |
| 266 | 24002EA | O | CORN GRAIN-ENDOSPERM | 0.351000 | 1.00 | 1.00 |
| 267 | 24002HA | O | CORN GRAIN-BRAN | 0.351000 | 1.00 | 1.00 |
| 268 | 24002SA | O | CORN GRAIN/SUGAR/HFCS | 0.351000 | 1.50 | 1.00 |
| 275 | 24006AA | O | SORGHUM (INCLUDING MILO) | 0.039000 | 1.00 | 1.00 |
| 289 | 27002OA | O | CORN GRAIN-OIL | 4.280000 | 1.00 | 1.00 |
| 321 | 53001BA | U | BEEF-MEAT BYPRODUCTS | 0.000162 | 1.00 | 1.00 |
| 322 | 53001BB | U | BEEF-OTHER ORGAN MEATS | 0.000162 | 1.00 | 1.00 |
| 324 | 53001FA | U | BEEF-FAT W/O BONES | 0.000297 | 1.00 | 1.00 |
| 325 | 53001KA | U | BEEF-KIDNEY | 0.000162 | 1.00 | 1.00 |
| 326 | 53001LA | U | BEEF-LIVER | 0.000162 | 1.00 | 1.00 |
| 368 | 55015MA | V | CHICKEN-FAT W/O BONES | 0.000352 | 1.00 | 1.00 |
| 388 | 24002MO | O | CORN GRAIN/SUGAR-MOLASSES | 0.351000 | 1.50 | 1.00 |



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U.S. Environmental Protection Agency — Ver. 6.12
DEEM89N CHRONIC analysis for PIRIMIPHOS-METHYL — (1989-92 data)
Residue file name: CHRONIC — Adjustment factor #2 NOT used.
Analysis Date 07-21-1998 — Residue file dated: 07-21-1998/11:38:31/8
Reference dose (RfD, CHRONIC) = 0.000250 mg/kg body-wt/day
COMMENT 1: The chronic NOEL is actually a LOEL
COMMENT 2: RfD incorporates OP Marathon Conclusions

Total exposure by population subgroup

| Population Subgroup | Total Exposure mg/kg body wt/day | Total Exposure Percent of Rfd |
|---|---|---|
| U.S. Pop - 48 states - all seasons | 0.000564 | 225.5% |
| U.S. Population - spring season | 0.000549 | 219.7% |
| U.S. Population - summer season | 0.000588 | 235.4% |
| U.S. Population - autumn season | 0.000575 | 230.1% |
| U.S. Population - winter season | 0.000539 | 215.7% |
| Northeast region | 0.000527 | 210.9% |
| Midwest region | 0.000575 | 230.0% |
| Southern region | 0.000594 | 237.6% |
| Western region | 0.000536 | 214.5% |
| Pacific Region | 0.000505 | 201.9% |
| Hispanics | 0.000598 | 239.3% |
| Non-hispanic whites | 0.000550 | 220.0% |
| Non-hispanic blacks | 0.000632 | 252.8% |
| Non-hispanic other than black or white | 0.000544 | 217.7% |
| All infants (<1 year) | 0.000685 | 273.8% |
| Nursing infants (<1 year) | 0.000217 | 86.6% |
| Non-nursing infants (<1 year) | 0.000882 | 352.6% |
| Children (1-6 years) | 0.001262 | 504.6% |
| Children (7-12 years) | 0.000975 | 390.0% |
| Females (13-19 yrs/not preg. or nursing) | 0.000568 | 227.1% |
| Females (20+ years/not preg. or nursing) | 0.000386 | 154.3% |
| Females (13-50 years) | 0.000441 | 176.5% |
| Females (13+/pregnant/not nursing) | 0.000425 | 170.0% |
| Females (13+/nursing) | 0.000465 | 186.1% |
| Males (13-19 years) | 0.000714 | 285.4% |
| Males (20+ years) | 0.000423 | 169.3% |
| Seniors (55+) | 0.000342 | 136.7% |

U.S. Environmental Protection Agency
DEEM89N CHRONIC analysis for PIRIMIPHOS-METHYL
Residue file name: CHRONIC
Analysis Date 07-21-1998
Reference dose (RfD, CHRONIC) = 0.000250 mg/kg body-wt/day
COMMENT 1: The chronic NOEL is actually a LOEL
COMMENT 2: RfD incorporates OP Marathon Conclusions

Ver. 6.12
(1989-92 data)
Adjustment factor #2 NOT used.
Residue file dated: 07-21-1998/11:38:31/8

Complete commodity contribution analysis for
U.S. Pop - 48 states - all seasons

Crop Group = (O) CEREAL GRAINS

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| CORN/POP | 0.351000 | 1.00 | 1.00 | 0.0000083 | 3.3% |
| CORN GRAIN-ENDOSPERM | 0.351000 | 1.00 | 1.00 | 0.0000734 | 29.4% |
| CORN GRAIN-BRAN | 0.351000 | 1.00 | 1.00 | 0.0000009 | 0.4% |
| CORN GRAIN/SUGAR/HFCS | 0.351000 | 1.50 | 1.00 | 0.0003496 | 139.9% |
| SORGHUM (INCLUDING MILO) | 0.039000 | 1.00 | 1.00 | no exposure | |
| CORN GRAIN-OIL | 4.280000 | 1.00 | 1.00 | 0.0001312 | 52.5% |
| CORN GRAIN/SUGAR-MOLASSES | 0.351000 | 1.50 | 1.00 | 0.0000003 | 0.1% |
| Crop group subtotal | | | | 0.0005638 | 225.5% |

Crop Group = (U) RED MEAT

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| BEEF-MEAT BYPRODUCTS | 0.000162 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-OTHER ORGAN MEATS | 0.000162 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-FAT W/O BONES | 0.000297 | 1.00 | 1.00 | 0.0000001 | 0.0% |
| BEEF-KIDNEY | 0.000162 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-LIVER | 0.000162 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| Crop group subtotal | | | | 0.0000001 | 0.0% |

Crop Group = (V) POULTRY

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| CHICKEN-FAT W/O BONES | 0.000352 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| Crop group subtotal | | | | 0.0000000 | 0.0% |
| Population subgroup total | | | | 0.0005638 | 225.5% |



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U.S. Environmental Protection Agency Ver. 6.12
DEEM89N CHRONIC analysis for PIRIMIPHOS-METHYL (1989-92 data)
Residue file name: CHRONIC Adjustment factor #2 NOT used.
Analysis Date 07-21-1998 Residue file dated: 07-21-1998/11:38:31/8
Reference dose (RfD, CHRONIC) = 0.000250 mg/kg body-wt/day
COMMENT 1: The chronic NOEL is actually a LOEL
COMMENT 2: RfD incorporates OP Marathon Conclusions

Complete commodity contribution analysis for
All infants (<1 year)

Crop Group = (O) CEREAL GRAINS

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| CORN/POP | 0.351000 | 1.00 | 1.00 | no exposure | |
| CORN GRAIN-ENDOSPERM | 0.351000 | 1.00 | 1.00 | 0.0000441 | 17.6% |
| CORN GRAIN-BRAN | 0.351000 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| CORN GRAIN/SUGAR/HFCS | 0.351000 | 1.50 | 1.00 | 0.0005530 | 221.2% |
| SORGHUM (INCLUDING MILO) | 0.039000 | 1.00 | 1.00 | no exposure | |
| CORN GRAIN-OIL | 4.280000 | 1.00 | 1.00 | 0.0000875 | 35.0% |
| CORN GRAIN/SUGAR-MOLASSES | 0.351000 | 1.50 | 1.00 | 0.0000000 | 0.0% |
| Crop group subtotal | | | | 0.0006846 | 273.8% |

Crop Group = (U) RED MEAT

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| BEEF-MEAT BYPRODUCTS | 0.000162 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-OTHER ORGAN MEATS | 0.000162 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-FAT W/O BONES | 0.000297 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-KIDNEY | 0.000162 | 1.00 | 1.00 | no exposure | |
| BEEF-LIVER | 0.000162 | 1.00 | 1.00 | no exposure | |
| Crop group subtotal | | | | 0.0000000 | 0.0% |

Crop Group = (V) POULTRY

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| CHICKEN-FAT W/O BONES | 0.000352 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| Crop group subtotal | | | | 0.0000000 | 0.0% |
| Population subgroup total | | | | 0.0006846 | 273.8% |



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U.S. Environmental Protection Agency Ver. 6.12
DEEM89N CHRONIC analysis for PIRIMIPHOS-METHYL (1989-92 data)
Residue file name: CHRONIC Adjustment factor #2 NOT used.
Analysis Date 07-21-1998 Residue file dated: 07-21-1998/11:38:31/8
Reference dose (RfD, CHRONIC) = 0.000250 mg/kg body-wt/day
COMMENT 1: The chronic NOEL is actually a LOEL
COMMENT 2: RfD incorporates OP Marathon Conclusions

Complete commodity contribution analysis for
Nursing infants (<1 year)

Crop Group = (O) CEREAL GRAINS

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| CORN/POP | 0.351000 | 1.00 | 1.00 | no exposure | |
| CORN GRAIN-ENDOSPERM | 0.351000 | 1.00 | 1.00 | 0.0000090 | 3.6% |
| CORN GRAIN-BRAN | 0.351000 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| CORN GRAIN/SUGAR/HFCS | 0.351000 | 1.50 | 1.00 | 0.0001910 | 76.4% |
| SORGHUM (INCLUDING MILO) | 0.039000 | 1.00 | 1.00 | no exposure | |
| CORN GRAIN-OIL | 4.280000 | 1.00 | 1.00 | 0.0000166 | 6.6% |
| CORN GRAIN/SUGAR-MOLASSES | 0.351000 | 1.50 | 1.00 | no exposure | |
| Crop group subtotal | | | | 0.0002166 | 86.6% |

Crop Group = (U) RED MEAT

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| BEEF-MEAT BYPRODUCTS | 0.000162 | 1.00 | 1.00 | no exposure | |
| BEEF-OTHER ORGAN MEATS | 0.000162 | 1.00 | 1.00 | no exposure | |
| BEEF-FAT W/O BONES | 0.000297 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-KIDNEY | 0.000162 | 1.00 | 1.00 | no exposure | |
| BEEF-LIVER | 0.000162 | 1.00 | 1.00 | no exposure | |
| Crop group subtotal | | | | 0.0000000 | 0.0% |

Crop Group = (V) POULTRY

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| CHICKEN-FAT W/O BONES | 0.000352 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| Crop group subtotal | | | | 0.0000000 | 0.0% |
| Population subgroup total | | | | 0.0002166 | 86.6% |



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U.S. Environmental Protection Agency Ver. 6.12
DEEM89N CHRONIC analysis for PIRIMIPHOS-METHYL (1989-92 data)
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Analysis Date 07-21-1998 Residue file dated: 07-21-1998/11:38:31/8
Reference dose (RfD, CHRONIC) = 0.000250 mg/kg body-wt/day
COMMENT 1: The chronic NOEL is actually a LOEL
COMMENT 2: RfD incorporates OP Marathon Conclusions

Complete commodity contribution analysis for
Non-nursing infants (<1 year)

Crop Group = (O) CEREAL GRAINS

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| CORN/POP | 0.351000 | 1.00 | 1.00 | no exposure | |
| CORN GRAIN-ENDOSPERM | 0.351000 | 1.00 | 1.00 | 0.0000588 | 23.5% |
| CORN GRAIN-BRAN | 0.351000 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| CORN GRAIN/SUGAR/HFCS | 0.351000 | 1.50 | 1.00 | 0.0007053 | 282.1% |
| SORGHUM (INCLUDING MILO) | 0.039000 | 1.00 | 1.00 | no exposure | |
| CORN GRAIN-OIL | 4.280000 | 1.00 | 1.00 | 0.0001174 | 46.9% |
| CORN GRAIN/SUGAR-MOLASSES | 0.351000 | 1.50 | 1.00 | 0.0000000 | 0.0% |
| Crop group subtotal | | | | 0.0008816 | 352.6% |

Crop Group = (U) RED MEAT

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| BEEF-MEAT BYPRODUCTS | 0.000162 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-OTHER ORGAN MEATS | 0.000162 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-FAT W/O BONES | 0.000297 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| BEEF-KIDNEY | 0.000162 | 1.00 | 1.00 | no exposure | |
| BEEF-LIVER | 0.000162 | 1.00 | 1.00 | no exposure | |
| Crop group subtotal | | | | 0.0000000 | 0.0% |

Crop Group = (V) POULTRY

| Food Name | Residue (ppm) | Adjustment Factors | | Exposure Analysis mg/kg body wt/day | Percent of RfD |
|---|---|---|---|---|---|
| CHICKEN-FAT W/O BONES | 0.000352 | 1.00 | 1.00 | 0.0000000 | 0.0% |
| Crop group subtotal | | | | 0.0000000 | 0.0% |
| Population subgroup total | | | | 0.0008816 | 352.6% |



11915

Acute

```
"pirimiphos-methyl"
 0.00025
NEW91,          0.0083
NOEL,           0.25          0.25          0
07-10-1998/10:29:17
-1  "The chronic NOEL is actually a LOEL"
 999                (Acute ARs)
 237   15004AA,O,   2.51        1             1          0  "CORN/POP", ""
 266   24002EA,O,   2.51        1             1          0  "CORN GRAIN-ENDOSPERM", ""
 267   24002HA,O,   2.51        1             1          0  "CORN GRAIN-BRAN", ""
 268   24002SA,O,   2.51        1.5           1          0  "CORN GRAIN/SUGAR/HFCS", ""
 275   24006AA,O,   3.9         1             1          0  "SORGHUM (INCLUDING MILO)", ""
 289   27002OA,O,   30.6        1             1          0  "CORN GRAIN-OIL", ""
 321   53001BA,U,   0.04        1             1          0  "BEEF-MEAT BYPRODUCTS", ""
 322   53001BB,U,   0.04        1             1          0  "BEEF-OTHER ORGAN MEATS", ""
 324   53001FA,U,   0.04        1             1          0  "BEEF-FAT W/O BONES", ""
 325   53001KA,U,   0.04        1             1          0  "BEEF-KIDNEY", ""
 326   53001LA,U,   0.04        1             1          0  "BEEF-LIVER", ""
 368   55015MA,V,   0.04        1             1          0  "CHICKEN-FAT W/O BONES", ""
 388   24002MO,O,   2.51        1.5           1          0  "CORN GRAIN/SUGAR-MOLASSES", ""
```

12915

U.S. Environmental Protection Agency
DEEM ACUTE analysis for PIRIMIPHOS-METHYL
Residue file name: acute.R91
Analysis Date: 07-10-1998/11:11:19
Acute Reference Dose (aRfD) = 0.008300 mg/kg body-wt/day
Run Comment: The chronic NOEL is actually a LOEL

Ver. 6.27
(1989-92 data)
Adjustment factor #2 NOT used.
Residue file dated: 07-10-1998/10:29:17/8

U.S. pop - all seasons

Daily Exposure Analysis 1/
(mg/kg body-weight/day)

| | per Capita | per User |
|---|---|---|
| Mean | 0.004035 | 0.004069 |
| Standard Deviation | 0.004300 | 0.004302 |
| Standard Error | 0.000023 | 0.000023 |
| Percent of aRfD | 48.61 | 49.02 |

Percent of Person-Days that are User-Days = 99.16%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding percent of aRfD

| Percentile | Exposure | % aRfD | Percentile | Exposure | % aRfD |
|---|---|---|---|---|---|
| 90.00 | 0.000662 | 7.98 | 10.00 | 0.008772 | 105.68 |
| 80.00 | 0.001185 | 14.28 | 5.00 | 0.011915 | 143.55 |
| 70.00 | 0.001702 | 20.50 | 2.50 | 0.015577 | 187.68 |
| 60.00 | 0.002243 | 27.02 | 1.00 | 0.020496 | 246.94 |
| 50.00 | 0.002861 | 34.47 | 0.50 | 0.025268 | 304.44 |
| 40.00 | 0.003602 | 43.40 | 0.25 | 0.029391 | 354.11 |
| 30.00 | 0.004549 | 54.81 | 0.10 | 0.035649 | 429.50 |
| 20.00 | 0.006054 | 72.94 | | | |

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding percent of aRfD

| Percentile | Exposure | % aRfD | Percentile | Exposure | % aRfD |
|---|---|---|---|---|---|
| 90.00 | 0.000612 | 7.37 | 10.00 | 0.008749 | 105.41 |
| 80.00 | 0.001150 | 13.86 | 5.00 | 0.011888 | 143.23 |
| 70.00 | 0.001671 | 20.13 | 2.50 | 0.015546 | 187.30 |
| 60.00 | 0.002215 | 26.69 | 1.00 | 0.020468 | 246.60 |
| 50.00 | 0.002834 | 34.15 | 0.50 | 0.025228 | 303.95 |
| 40.00 | 0.003577 | 43.09 | 0.25 | 0.029356 | 353.69 |
| 30.00 | 0.004525 | 54.52 | 0.10 | 0.035613 | 429.08 |
| 20.00 | 0.006028 | 72.63 | | | |

1/ Analysis based on all three-day participant records in CSFII 1989-92 survey.



U.S. Environmental Protection Agency
DEEM ACUTE analysis for PIRIMIPHOS-METHYL
Residue file name: acute.R91
Analysis Date: 07-10-1998/11:11:19
Acute Reference Dose (aRfD) = 0.008300 mg/kg body-wt/day

Ver. 6.27
(1989-92 data)
Adjustment factor #2 NOT used.
Residue file dated: 07-10-1998/10:29:17/8

Nursing infants (<1 year)

Daily Exposure Analysis
(mg/kg body-weight/day)

| | per Capita | per User |
|---|---|---|
| Mean | 0.001554 | 0.004144 |
| Standard Deviation | 0.002415 | 0.002195 |
| Standard Error | 0.000195 | 0.000339 |
| Percent of aRfD | 18.72 | 49.93 |

13915

Estimated percentile of per-capita days exceeding calculated exposure
in mg/kg body-wt/day and corresponding percent of aRfD

| Percentile | Exposure | % aRfD | Percentile | Exposure | % aRfD |
|---|---|---|---|---|---|
| 90.00 | 0.000000 | 0.00 | 10.00 | 0.018716 | 225.49 |
| 80.00 | 0.000000 | 0.00 | 5.00 | 0.022065 | 265.84 |
| 70.00 | 0.000000 | 0.00 | 2.50 | 0.027199 | 327.70 |
| 60.00 | 0.000543 | 6.54 | 1.00 | 0.042357 | 510.33 |
| 50.00 | 0.001211 | 14.59 | 0.50 | 0.070688 | 851.66 |
| 40.00 | 0.003845 | 46.32 | 0.25 | 0.110919 | 1336.37 |
| 30.00 | 0.007086 | 85.37 | 0.10 | 0.144424 | 1740.05 |
| 20.00 | 0.011619 | 139.99 | | | |



U.S. Environmental Protection Agency Ver. 6.27
DEEM ACUTE analysis for PIRIMIPHOS-METHYL (1989-92 data)
Residue file name: acute.R91 Adjustment factor #2 NOT used.
Analysis Date: 07-10-1998/11:11:19 Residue file dated: 07-10-1998/10:29:17/8
Acute Reference Dose (aRfD) = 0.008300 mg/kg body-wt/day

Children (1-6 years)

Daily Exposure Analysis (mg/kg body-weight/day)

| | per Capita | per User |
|---|---|---|
| Mean | 0.009026 | 0.009034 |
| Standard Deviation | 0.006879 | 0.006876 |
| Standard Error | 0.000111 | 0.000111 |
| Percent of aRfD | 108.74 | 108.85 |

Percent of Person-Days that are User-Days = 99.90%

Estimated percentile of user-days exceeding calculated exposure
in mg/kg body-wt/day and corresponding percent of aRfD

| Percentile | Exposure | % aRfD | Percentile | Exposure | % aRfD |
|---|---|---|---|---|---|
| 90.00 | 0.002191 | 26.40 | 10.00 | 0.017583 | 211.84 |
| 80.00 | 0.003669 | 44.21 | 5.00 | 0.022583 | 272.08 |
| 70.00 | 0.004833 | 58.23 | 2.50 | 0.026822 | 323.16 |
| 60.00 | 0.006238 | 75.16 | 1.00 | 0.033102 | 398.82 |
| 50.00 | 0.007451 | 89.77 | 0.50 | 0.037035 | 446.21 |
| 40.00 | 0.008863 | 106.78 | 0.25 | 0.040480 | 487.72 |
| 30.00 | 0.010901 | 131.33 | 0.10 | 0.052169 | 628.54 |
| 20.00 | 0.013407 | 161.53 | | | |

Estimated percentile of per-capita days exceeding calculated exposure
in mg/kg body-wt/day and corresponding percent of aRfD

| Percentile | Exposure | % aRfD | Percentile | Exposure | % aRfD |
|---|---|---|---|---|---|
| 90.00 | 0.002172 | 26.17 | 10.00 | 0.017579 | 211.79 |
| 80.00 | 0.003658 | 44.07 | 5.00 | 0.022578 | 272.03 |
| 70.00 | 0.004825 | 58.13 | 2.50 | 0.026818 | 323.11 |
| 60.00 | 0.006230 | 75.06 | 1.00 | 0.033098 | 398.77 |
| 50.00 | 0.007445 | 89.70 | 0.50 | 0.037031 | 446.16 |
| 40.00 | 0.008857 | 106.71 | 0.25 | 0.040477 | 487.68 |
| 30.00 | 0.010895 | 131.26 | 0.10 | 0.052161 | 628.45 |
| 20.00 | 0.013403 | 161.48 | | | |

Summary calculations:

| | 95th Percentile Exposure | 95th Percentile % aRfD | 99th Percentile Exposure | 99th Percentile % aRfD | 99.9 Percentile Exposure | 99.9 Percentile % aRfD |
|---|---|---|---|---|---|---|
| U.S. pop - all seasons: | 0.011888 | 143.23 | 0.020468 | 246.60 | 0.035613 | 429.08 |
| Nursing infants (<1 year): | 0.007220 | 86.99 | 0.008961 | 107.97 | 0.009260 | 111.57 |
| Non-nursing infants (<1 yr): | 0.022065 | 265.84 | 0.042357 | 510.33 | 0.144424 | 1740.05 |
| Children (1-6 years): | 0.022578 | 272.03 | 0.033098 | 398.77 | 0.052161 | 628.45 |
| Children (7-12 years): | 0.016447 | 198.16 | 0.024378 | 293.71 | 0.040685 | 490.18 |